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GROUP 1600

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**New Avenues in Nervous System Research**

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Total number of pages: 7 Detailed

Regarding: Response to Action 9/800, 870 Filed 3-7-01

Comments:

**6-30-03 Inventor Response to DETAILED ACTION**

REPLY:

Claim 10 needs to be considered since it refers to products directly dependent on this model: such as cellular or tissue specimens ( in-vitro and in-vivo) obtainable from the model once it is created in a animal and the databases related to it's unique physiological processes. The creation of such products are dependent on the unique methods used in this invention. "Product" here refers to anything produced or made from the model or its unique biological data either naturally or artificially (Stedman's Medical Dictionary 4.0).

Claim 11 needs to be considered since it refers to products derived from Claim 10; such as drugs, treatments, unique cell detection assays or microarrays derived from cells, tissues or biological databases dependent on the unique physiological data of this model. Cell assays would include tests such as microarrays or other evaluations derived from and dependent on specific properties of this model. Such assays could be used as detectors for unique proteins, luminescence or antibody properties of this model.

The products in claims 10 and 11 are dependent and integral to the unique properties of the methods and model as described in this invention of a method for creating an animal model of human pain.

*Detailed Action: Election/Restrictions for reference*
*"Restriction to one of the following inventions is required under 35 U.S.C. 121:*

I. *Claims 1-4 and 6-9, drawn to a method for producing non-destructive nerve alternations in an animal, classified in class 800, subclass 8.*
II. *Claim 5, drawn to an animal model wherein compression is placed around a nerve non-surgically, classified in class 800, subclass 8.*
III. *Claims 12-15, drawn to a method of screening treatments using a model of pain, classified in various classes and subclasses.*
IV. *Claims 16-17, drawn to a composition for treatment of pain, classified in various classes and subclasses."*

REPLY: The above groups are dependent and indistinct, each from the other as an invention because of the following reasons:

*The Invention as described should be classified in Class 800, subclass 9 :*
*"The nonhuman animal is a model for human disease"*
*This subclass is indented under subclass 8.*
*Subject matter wherein the nonhuman animal mimics a human disease state either continuously or in response to a particular condition or treatment.*

A. Inventions I and II are patentably indistinct because, the methods of Group I require the method of Group II. Nonsurgical placement or creation of a compression with collagen has been described in the description of the present invention and the method in Group II does not exists in any other animal models for human pain. The search required for the methods of making non-destructive nerve alterations and the animal model wherein compression is placed around a nerve are related. The scope of placing compression on a nerve non-surgically (claim 5) is similar in scope to the methods of claims 1-4 and 6-9. The burden required to search Groups I and II together is limited since the groups are dependent and related.

B. Inventions I, II and III are patentably indistinct because, the methods of Group III to scre n for treatments of chronic pain can only be performed using the methods of

creating the model as described in Group I and II above. The methods of Group III are dependent on Groups I and II, in determining a model for a human disease state. The protocols required for Group III are dependent and indistinct from Groups I and II, since screening tests using this model could not exist without using the methods as described in Groups I, II and III in defining an animal model of a human pain state related to a bodily dysfunction. The burden required to search Groups I, II and III together is limited since they are dependent and the literature and patents are few for animal models of human pain.

C. Inventions I, II, III and IV are patentably indistinct because, the methods of Group I and II can be used to generate an unique animal model while the composition and reaction of Group IV is directly dependent on the unique model created by Groups I and II, and on the screening of any substances to be used to treat chronic pain in Group III. The method of Groups I, II and III are necessary for the composition of the treatment in Group IV and the composition of Group IV is necessary and dependent on the methods of Groups I,II and III in determining "*response to a particular condition or treatment*" in this animal model mimicking human pain.

The burden required to search Groups I, II, III and IV together would be limited and reasonable since they dependent. The literature and patents related to animal models of human pain is limited.

D. Inventions II and III are patentably indistinct because, the method of Group II is used to create the model in Group I, and this model is then used to screen for treatments for chronic pain as in Group III. The protocols and reagents required for the

method of creating the animal model and the method of screening are materially indistinct and dependent, since the unique model for screening as described in this invention could not exist without the methods described in Groups I and II. The animal model as described in Groups I and II is necessary for the unique methods of screening in Group III and the methods of use as described in Group III are necessary and dependent on the methods of creating this novel model of the human dysfunctional state of pain. The burden required to search Groups I, II and III together would be limited and reasonable since they dependent. The literature and patents related to animal models of human pain is limited.

E. Inventions II and IV are patentably indistinct because, the methods of Group II can be used to create animal models of chronic pain unique to the methods of Groups I and II; while the composition of the treatment Group IV is dependent on the chronic pain as described in Groups I and II. The protocols and reagents required for the method of creating the pain behavior (Groups I and II) and the creation of the model for treatment (Group IV) are materially indistinct and related, since treatments are integral to defining an animal model of pain.

Treatments are necessary to reverse the bodily dysfunction of pain and to define an animal model of a disease state. The creation of the animal model is necessary for the treatment and the treatment is necessary for the animal model as defined in : wherein the nonhuman animal mimics a human disease state either continuously or in response to a particular condition or treatment (Classification 800/9). Th⁻ burden required to search Groups II and IV together is not extensive since the groups are

dependent. The literature and patents related to animal models of human pain is limited.

F. Inventions III and IV are patentably indistinct because, the methods of Group III can be used to identify treatments of chronic pain while the composition of Group IV can be used to treat chronic pain as defined in Classification 800/9. The protocols and reagents required for the methods and the composition are materially indistinct and related to developing the unique response to a particular condition or treatment by this novel model. The methods of Group III are necessary to screen efficacious treatments for chronic pain in this model and the compositions for creating the method to treat chronic pain as described in Group IV is necessary to determine reversal of pain in response to treatment. The burden required to search Groups III and IV together would be limited since these groups are both dependent, and the literature and patents related to animal models of human pain is limited.

Because the methods in Groups I,II,III and IV and claims 10, and 11 are indistinct for the reasons given above and maintain a dependent and unified status in the art as shown by their dependent classification in 800/9 as a nonhuman animal model mimicking a disease state with a response to a particular condition or treatment, and their recognized related subject matter, and because the searches for the groups are limited, restriction for examination purposes as indicated is not proper.

ELECTION of the invention from Groups I,II,III and IV as required:

This applicant elects Group I as described by claims 1-4 and 6-9 to be the invention examined, even though the applicant denies the restrictions of this requirement (37 CFR 1.143). as defined under Classification 800/9.

Any inquiry concerning this communication should be directed to Mary H. Romans whose telephone number is 817-738-9990; Fax: 817-738-9467; e-mail: hannaman@neurodigm.com.